REMARKS

The present communication responds to the final Office Action of June 4, 2004. In that Office Action, the Examiner rejected claims 28-75. The present communication amends the pending independent claims 28, 46, 55, 64, 66 and 67. In view of these amendments, which clarify the claimed invention, and for the reasons set forth below, the rejections are traversed and reconsideration is respectfully requested.

The claimed invention is an apparatus for subcutaneous administration of an injectable product, wherein the apparatus comprises a needle protection sleeve and an indicator which indicates to a user, during insertion of a needle for injection, that the sleeve is in a certain position. It is respectfully submitted that this is not disclosed or taught by the cited references.

Rejection under 35 U.S.C. § 102

Claims 55, 59-69, 72-75 were rejected under 35 U.S.C. § 102(b) as being anticipated by U.S. Patent 5,873,856 to Hijertman et al. or U.S. Patent 5,674,203 to Lewandowski or U.S. Patent 6,547,764 to Larsen et al. This rejection is traversed for the following reasons.

As discussed in the remarks accompanying the July 9, 2003 Request for Continued Examination, there appears to be some confusion with respect to what the Hjertman et al. reference discloses. For example, rather than an "indicator" as asserted by the Examiner, element 33 of the Hjertman et al. device is a "flange." *Hjertman et al, column 2, line 51.* Similarly, it is not clear how the Hjertman et al. reference discloses or teaches an "outer sleeve" and a "needle protection sleeve" both identified as element "31" by the Examiner. Element 31 of Hjertman et al. is actually an "annular stopping flange." *Hjertman et al., column 3, line 30.*

An even more fundamental flaw with respect to any rejection based on the Hjertman et al. reference is that it simply does not disclose or teach an indicator for indicating to the user of an injection device that a sleeve associated with the device is in a certain position during insertion of a needle for injection of a product. What Hjertman et al. does disclose is a stopping means 24 which cooperates with a flange 31 to limit the penetration depth of a needle and how to set the penetration depth by axially displacing a stopping sleeve 40. *Hjertman et al., column 2, lines 57-*

60 and column 4, lines 22-23. Hjertman et al. does not teach or suggest an indicator for indicating that a needle protection sleeve has attained its distal position during insertion of a needle for injection of a product.

As each of claims 55, 64, 66 and 67 recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of the needle for an injection and as each of claims 59-63, 65, 68-69 and 72-75 depend from these claims, it is respectfully submitted that claims 55, 59-69, 72-75 are patentable over the Hjertman et al. reference. Accordingly, it is respectfully requested that the rejection of claims 55, 59-69 and 72-75 as anticipated by Hjertman et al. be withdrawn.

Upon reviewing the rejection, the applicant notes that the Examiner refers to Figures 7-9 of the Larsen et al. reference, but that the Larsen et al. reference actually includes only eight figures. Further review of the Examiner's citation of the Larsen et al. and Lewandowski et al. references shows that the Examiner mistakenly referred to the Larsen et al. reference while asserting her interpretation of the Lewandowski et al. reference and referred to the Lewandowski et al. reference while describing her interpretation of the Larsen et al. reference. Thus, the applicant's discussion of the rejection assumes that the descriptions were reversed.

The Examiner asserts that the Lewandowski et al. reference discloses each of the elements recited in claims 55, 59-69 and 72-75 including an indicator 55/51/38/84 (apparently the Examiner meant element 83 rather than element 38) which "indicates to a user that a needle protection sleeve is in its distal position." The Examiner states: "An indicator, which is visibly [sic], indicates to the user of the apparatus." However, the Examiner does not explain what the indicator of Lewandowski et al. visibly indicates to the user of the apparatus. This rejection is traversed for the following reasons.

As amended, the independent claims of the present application each recite an indicator which indicates to the user of the apparatus that the needle protection sleeve is in the distal position during insertion of the injection needle, for example during injection or administration of the injectable product. This is not disclosed or taught by Lewandowski et al.

The Lewandowski et al. reference describes a safety indicator means which visibly indicates when a needle guard is not locked in the extended position. *Lewandowski et al., column 4, lines 62-64.* Lewandowski et al. explain that the syringe is safe for transporting to a disposal device when the needle guard is in its fully extended and locked position and that:

> in order to be sure that the needle guard is fully extended and locked, a person finding the syringe in an apparently safe locked condition would have to physically apply a force to the needle guard in a proximal direction to assure that it was locked. If the needle guard is not in a locked position it would move in a proximal direction with respect to the barrel further exposing the needle and possibly exposing the user to an accidental needle stick. *Lewandowski et al, column 4, lines 46-48, 51-61.*

In contrast, the indicator of the present invention indicates retraction of the needle protection sleeve – or that the needle protection is in the distal position during insertion of a needle for injection:

> In accordance with the present invention, the apparatus comprises an indicator which on insertion of the injection needle and a retraction of the needle protection sleeve involved, indicates to the user whether, or that, the needle protection sleeve has attained its distal position. *Present application, page 3.*

The indicator of the Lewandowski et al. reference does not indicate the position of the needle guard, it indicates whether the needle guard is locked. Thus, for example, the indicator may indicate that the needle guard is not locked although it is in an extended position. Likewise, the indicator may indicate that the needle guard is not locked when it is in a non-extended position. Lewandoski et al. do not teach or suggest an indicator for indicating that a needle protection sleeve has attained its distal position during insertion of a needle for injection.

As each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for administration or injection of a product, and as each of the remaining claims depend from these claims, it is respectfully submitted that the presently pending claims are patentable over the Lewandowski et al. reference. Accordingly, it is respectfully requested that the rejection of claims 55, 59-69, 72-75 as anticipated by Lewandowski et al. be withdrawn.

The Examiner also asserts that the Larsen et al. reference discloses each of the elements recited in claims 55, 59-69 and 72-75. Specifically, the Examiner asserts that Larsen et al. (at

Col. 11, line 45-60 and in claim 1) discloses an indicator which indicates to a user that a needle protection sleeve is in its distal position. This rejection is traversed for the following reasons.

> Larsen et al. teach an indicator for indicating when an injection needle has been used:
>
> In order to provide the user with a clear visible indication that the injection needle has been used, the safety shield 10 can be provided with at least one transparent area 32 ...When the injection needle is in the initial position ready to be inserted into the human body, the projection 22 is located in the first part 27 of the track 18. In this position the first area 33 on the outside surface of the hub 4 is visible through the transparent area 32 of the safety shield 10. After the injection, the projection 22 is located in the hole or well 31, and the transparent area 32 of the safety shield 10 is dislocated such that the second area 34 is now visible through the transparent area. *Larsen et al., column 11, lines 48-50, lines 66-67 and column 12, lines 1-7.*

Larsen et al. explain that the indicator indicates that the injection needle has been used and that the needle protector is in a position protecting the needle so that it can be safely removed:

> The short and thin injection needle is provided with a movable needle protector which allows normal use of the injection needle during injection, and which movable needle protector once the injection is done can be shifted manually or automatically into a position where the movable needle protector covers the skin piercing end of the needle cannula in an irreversible manner. When the skin-piercing end of the cannula is covered, the injection needle can be removed from the syringe and disposed of without endangering the people performing the injection and the people disposing of the used injection needles. *Larsen et al., column 4, lines 1-10.*

Thus, Larsen et al. disclose an indicator for indicating that the needle has been used and is safely protected for disposal. Larsen et al. do not teach or suggest an indicator which visibly indicates to the user of the apparatus that the needle protection sleeve is in the distal position during insertion of the injection needle during insertion of a needle for an injection or administration of an injectable product.

As each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of the injection needle, for example for administration or injection of an injectable product, and as each of the remaining claims depend from these claims, it is respectfully submitted that the pending claims are patentable over the Larsen et al. reference. Accordingly, it is respectfully requested that the rejection of claims 55, 59-69, 72-75 as anticipated by Larsen et al. be withdrawn.

Rejection under 35 U.S.C. § 103

Claims 28-54, 56-58, 70-71 were rejected under 35 U.S.C. § 103(a) as unpatentable over Hjertman et al. or Lewandowski, and further in view of U.S. Patent 6,287,283 to Ljunggreen et al. or U.S. Patent Publication No. 2002/0002344A1 to Douglas et al. This rejection is traversed for the following reasons.

As discussed above, neither Hjertman et al. nor Lewandowski et al. teach or disclose an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for injection or administration of an injectable product. Neither Ljunggreen et al. nor Douglas et al. teach this and, therefore, even if proper, the asserted combinations would not make the claimed invention obvious.

The Ljunggreen et al. reference discloses an apparatus for the registration of the setting of a medical device, the setting of which implies a mechanical adjustment of at least two relatively moveable elements of the device. The object of the Ljunggreen et al. invention is to provide an apparatus for a more safe detecting of the setting of the medical device, for example, of the dosage measured for insulin administration. Thus, a further object is to provide a more safe reading of the pharmaceutical dosage given from a dosage unit. *See Ljunggreen et al., column 1, lines 50-55.* Ljunggreen et al. describes the apparatus as follows:

> an apparatus which is intended for disconnecting engagement with the medical device, said apparatus having detector means for detecting the selected setting and information means for providing information related to said mechanical adjustment. Preferably, the device may be a dosage unit ... When arranging the apparatus so that it can receive the first end of the dosage unit, whereby the adjustment of the dosage quantity is effected by revolving the dosage unit relatively to the apparatus, the apparatus according to the invention will function just like the removable cap of the well-known insulin pen whereby the users will feel comfortable when using the new apparatus with their own and well-known insulin pen. *Ljunggreen et al., Column 1, line 63 – Column 2, line 18.*

Thus, Ljunggreen et al. disclose a dosage indicator. Ljunggreen et al. does not teach or suggest indicating the position of a needle protection sleeve during insertion of a needle for injection or administration of an injectable product.

The Douglas et al. reference discloses lancing devices and methods for obtaining samples of blood and other fluids from the body for analysis or processing. *Douglas et al., paragraph [0002]*. One of the objects of the invention of the Douglas et al. reference is "to ensure that a sufficiently large drop of body fluid is developed at an incision, and that the body fluid reaches a test strip." *Douglas et al., paragraph [0020]*. Douglas et al. explains that a problem facing users is determining whether a drop size is sufficient for analysis, the invention purports to solve this problem:

> One problem faced by a user is being able to determine whether a drop of body fluid expressed from an incision is of sufficient size to provide a proper sample. That determination can be made automatically by a sampling device 10'' in accordance with an embodiment of the invention depicted in FIG. 6 wherein a drop sensing mechanism 65 is mounted on an inner sleeve 66. *Douglas et al., paragraph [0061]*.

Thus, Douglas et al. disclose a drop sensing mechanism. Douglas et al. does not teach or suggest indicating the position of a needle protection sleeve during insertion of a needle for injection or administration of an injectable product.

Thus, even if one skilled in the art were to consider the combined teaching of the combination proposed by the Examiner, the result would not produce an insertion apparatus for the administration or injection of an injectable product including an indicator that shows that a needle protection sleeve has attained a certain position during insertion of the needle for injection or administration of the product.

As each of the independent claims recite an indicator indicating that a needle protection sleeve has attained its distal position during insertion of a needle, for example for injection or administration of an injectable product, and as each of remaining claims depend from these claims, it is respectfully submitted that the pending claims are not taught be the asserted combinations. Accordingly, it is respectfully requested that the rejection of 28-54, 56-58, 70-71 under 35 U.S.C. § 103(a) be withdrawn.

Conclusion

Applicant submits herewith a Petition for Extension of Time along with the appropriate fee. The Commissioner is hereby authorized to charge any deficiency and/or credit any overpayment to Deposit Account No. 04-1420.

This application is in allowable form, and reconsideration and allowance are respectfully requested.

Respectfully submitted,

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